

Exhibit A



Nov 19 2007
5:06PM

**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, CHANCERY DIVISION**

THE PEOPLE OF THE STATE OF ILLINOIS,)	
)	
Plaintiff,)	
)	No. 05 CH 2474
v.)	
)	The Honorable Peter Flynn
ABBOTT LABORATORIES, INC., et al.,)	
)	
Defendants.)	

**DEFENDANTS' JOINT MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT**

Helen E. Witt, P.C.
Elizabeth S. Hess
Ceylan A. Eatherton
Miriam L. Lieberman
KIRKLAND & ELLIS LLP
Firm No. 90443
200 East Randolph Drive
Chicago, Illinois 60601
Telephone: (312) 861-2000
Facsimile: (312) 861-2200

*Attorneys for Defendants
Ben Venue Laboratories, Inc.,
Boehringer Ingelheim Pharmaceuticals, Inc.,
and Boehringer Ingelheim Roxane, Inc. and
on behalf of all joining Defendants*

November 19, 2007

TABLE OF CONTENTS

	Page
I. THE DEPARTMENT OF HEALTHCARE AND FAMILY SERVICES HAS PRIMARY JURISDICTION TO REVIEW THE STATE’S CLAIMS. (735 ILCS § 5/2-619(a)(1)).....	6
II. ALL COUNTS SHOULD BE DISMISSED BECAUSE THE AMENDED COMPLAINT FAILS TO SATISFY ILLINOIS FACT PLEADING REQUIREMENTS. (735 ILCS § 5/2-615).....	10
A. The State Has Failed To Allege What Was Fraudulent About The AWP’s Reported For Defendants’ Drugs.	11
B. The State Has Failed To Allege A Duty Owed By Defendants Not To Report AWP’s That Exceeded Actual Acquisition Cost By More Than The State’s Discount Percentage.....	17
C. The State Has Failed To Specify Each Defendant’s Role In The Alleged Fraud.	18
III. COUNTS I AND II SHOULD BE DISMISSED BECAUSE THE STATE FAILS TO STATE A CLAIM UNDER THE CONSUMER FRAUD AND DECEPTIVE PRACTICES ACT. (735 ILCS § 5/2-615)	22
A. The State Has Not Adequately Alleged An Unfair Or Deceptive Act Or Practice, Intent, Or A Basis For Penalties.....	22
B. The State Has Not Pled The Advertisement And Offer To Sell Required To State A Claim Under Section 2CC(b).	24
C. The Prayers For Actual Damages In Counts I and II Should Be Dismissed Because The Attorney General Has No Standing To Bring Them.....	25
IV. COUNT III UNDER THE ILLINOIS PUBLIC ASSISTANCE FRAUD ACT SHOULD BE DISMISSED BECAUSE DEFENDANTS SUBMITTED NO “CLAIMS” FOR PAYMENT. (735 ILCS § 5/2-615).....	26
V. COUNT IV UNDER THE WHISTLEBLOWER REWARD AND PROTECTION ACT FAILS BECAUSE DEFENDANTS SUBMITTED NO “CLAIMS” FOR PAYMENT. (735 ILCS § 5/2-615)	27
VI. THE STATE’S CLAIMS IN COUNT IV ARE BARRED IN PART BY THE APPLICABLE STATUTE OF LIMITATIONS. (735 ILCS § 5/2-619(a)(5)).....	30

TABLE OF AUTHORITIES

Cases

<i>Acme Brick & Supply Co. v. Dep't. of Revenue</i> , 133 Ill. App. 3d 757 (2d Dist. 1985).....	13
<i>Baptist Hospital v. Tennessee Department of Health</i> , 982 S.W.2d 339 (Tenn. 1998).....	9
<i>Board of Education v. A, C & S, Inc.</i> , 131 Ill. 2d 428 (1989)	11, 18, 26
<i>Board of Managers of Chestnut Hills Condominium Ass'n v. Pasquinelli, Inc.</i> , 354 Ill. App. 3d 749 (1st Dist. 2004)	13
<i>Chatham Surgicore, Ltd. v. Health Care Serv. Corp.</i> , 356 Ill. App. 3d 795 (1st Dist. 2005)	10
<i>City of Shelbyville v. Shelbyville Restorium, Inc.</i> , 451 N.E.2d 874 (Ill. 1983).....	30
<i>Commw. ex rel. Pappert v. TAP Pharm. Prods., Inc.</i> , 868 A.2d 624, 636 (Pa. Commw. Ct. 2005)	20
<i>Connick v. Suzuki Motor Co.</i> , 174 Ill. 2d 482, 501 (1996)	18
<i>Donnells v. Woodridge Police Pension Board</i> , 159 Ill. App. 3d 735 (2d Dist. 1987).....	8
<i>Du Page Aviation Corp. v. Du Page Airport Authority</i> , 229 Ill. App. 3d 793 (1992)	26
<i>Edelman, Combs & Latturner v. Hinshaw & Culbertson</i> , 338 Ill. App. 3d 156 (1st Dist. 2003)	10
<i>Exchange Nat'l Bank v. Farm Bureau Life Ins. Co.</i> , 108 Ill. App. 3d 212, 215 (3d Dist. 1982).....	18
<i>Finish Line Express v. City of Chicago</i> , 72 Ill. 2d 131, 379 N.E.2d 290, 291 (1978).....	1
<i>Gouge v. Cent. Ill. Pub. Serv. Co.</i> , 144 Ill. 2d 535 (1991)	10
<i>Helfant v. Louisiana & Southern Life Insurance Co.</i> 459 F. Supp. 720 (E.D.N.Y. 1978)	11

<i>Hirsch v. Feuer</i> , 299 Ill. App. 3d 1076, 1081 (1st Dist. 1998)	10, 11
<i>Kellerman v. MCI Telecommunications Corp.</i> , 112 Ill. 2d 428 (1986)	9
<i>Kelly v. Sears Roebuck & Co.</i> , 308 Ill. App. 3d 633 (1st Dist. 1999)	11
<i>Louisiana v. Dep't of Health & Human Servs.</i> , 905 F.2d 877 (5th Cir. 1990)	14
<i>Martin v. Fed. Life Ins. Co.</i> , 109 Ill. App. 3d 596 (1st Dist. 1982)	10
<i>Nordine v. Illinois Power Co.</i> , 32 Ill. 2d 421 (1965)	13
<i>Pennsylvania Department of Public Welfare v. River Street Associates</i> , 798 A.2d 260 (Pa. Commw. Ct. 2002)	9, 10
<i>People ex rel. Hartigan v. E & E Hauling, Inc.</i> , 153 Ill. 2d 473, 492 (1992)	11
<i>People ex. rel. Levenstein v. Salafsky</i> , 338 Ill. App. 3d 936 (2d Dist. 2003)	29
<i>Petrich v. MCY Music World, Inc.</i> , 371 Ill. App. 3d 332, 343 (1st Dist. 2007)	18
<i>Robinson v. Toyota Motor Credit Corp.</i> , 201 Ill. 2d 403, 417 (2002)	22
<i>Scachitti v. UBS Financial Services</i> , 215 Ill. 2d 484 (2005)	27
<i>Schal Bovis, Inc. v. Cas. Ins. Co.</i> , 314 Ill. App. 3d 562 (1st Dist. 1999)	10
<i>Skłodowski v. Countrywide Home Loans, Inc.</i> , 358 Ill. App. 3d 696, (1st Dist. 2005)	10
<i>Sturm v. Block</i> , 72 Ill. App. 3d 306 (3d Dist. 1979)	13
<i>United States ex rel. Glass v. Medtronic, Inc.</i> , 957 F.2d 605 (9th Cir. 1992)	28

<i>United States ex rel. Grynberg v. Ernst & Young LLP</i> , 323 F. Supp. 2d 1152 (D. Wy. 2004).....	30
<i>United States ex rel. Hochman v. Nackman</i> , 145 F.3d 1069, 1075 (9th Cir. 1998)	28
<i>United States v. Bornstein</i> , 423 U.S. 303 (1976).....	29
<i>United States v. Bruno's Inc.</i> , 54 F. Supp. 2d 1252, 1260 (M.D. Ala. 1999)	28
<i>United States v. Southland Mgmt. Corp.</i> , 326 F.3d 669 (5 th Cir. 2003)	29
<i>Vicom, Inc. v. Harbridge Merch. Servs., Inc.</i> , 20 F.3d 771 (7 th Cir. 1994)	19
<i>White v. DaimlerChrysler Corp.</i> , 368 Ill. App. 3d 278, 286 (1st Dist. 2006)	23
<i>Wisconsin v. Amgen Inc.</i> , No. 04-CV-1709, slip op. at 13 (Wis. Cir. Ct. April 3, 2006).	18, 20

Statutes

13 Ill. Reg. 2475 (Feb. 14, 1989).....	1, 14
19 Ill. Reg. 9297 (July 1, 1995)	15
24 Ill. Reg. 10436 (July 1, 2000)	1, 2, 8, 16
24 Ill. Reg. 15086 (Oct. 1, 2000)	8, 16
25 Ill. Reg. 14957 (Nov. 1, 2001).....	15
26 Ill. Reg. 11259 (July 1, 2002)	15
305 ILCS § 5/12-13	9
305 ILCS § 5/5-5.12	7
305 ILCS § 5/8A-7(b).....	26
42 C.F.R. § 447.331	4
42 C.F.R. § 447.332	4

42 U.S.C. § 1395w-3a(c)(6)(B)	6
42 U.S.C. § 1396a(a)(30)(A)	4
42 U.S.C. § 1396r-8(a)(1), (b)(2) & (3)	5
42 U.S.C. § 1396r-8(c)(1) & (3)	5
42 U.S.C.A. § 1396a(a)5	7
735 ILCS § 5/13-202	30
735 ILCS § 5/2-603(a)	18
735 ILCS § 5/2-615	passim
735 ILCS § 5/2-619(a)(1)	2, 6
735 ILCS § 5/2-619(a)(5)	2, 30
815 ILCS § 505/1(c)	26
815 ILCS § 505/10a(A)	25
815 ILCS § 505/2	22
815 ILCS § 505/2CC	22
815 ILCS § 505/2CC(a)	25
815 ILCS § 505/7(b)	23, 24
815 ILCS § 505/7(c)	23, 24
89 ILL. ADMIN. CODE § 140.445	1
89 ILL. ADMIN. CODE tit. 89, § 119.60	5
ILL. ADMIN. CODE tit. 89 § 140.445	1

Other Authorities

Department of Health and Human Services, HCFA Program Memorandum, PM Rev AB-00-115 (Nov. 2000)	16
<i>Department of Health and Human Services, office of Inspector General, Medicare and Medicaid Guide (CCH) § 34,157 (Sept. 1984)</i>	14

GAO, “Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland,” (March 1993)	14
HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, Medicaid – Formula For Determining EAC For Drugs	14
<i>Medicare Action Transmittal No. 84-12</i>	1, 7

INTRODUCTION

For well over two decades, the federal government has repeatedly announced that the “Average Wholesale Price” (“AWP”) reported for drugs by certain pharmaceutical trade publications represent benchmark prices, “substantially higher than the prices for drugs actually paid by pharmacies.” Dep’t of Health & Human Servs., Office of Inspector Gen., *Medicare Action Transmittal No. 84-12*, (Sept. 1984) reprinted in *Medicare & Medicaid Guide* (CCH) ¶ 34,157 at 2 (Sept. 1984) (Ex. 1.).¹ By regulation, accordingly, the Illinois Medicaid program does not reimburse health care providers for prescription drugs at amounts equal to the published AWP. Instead, since 1989, the Medicaid program payment formulas either have not used AWP at all or have reimbursed providers at discounts – ranging from 7.5% to 25% off the published AWP. *See, e.g.*, 13 Ill. Reg. 2475, 2494 (Feb. 14, 1989); ILL. ADMIN. CODE tit. 89, § 140.445; (Am. Compl. ¶ 48.)² In fact, since 2000, the State’s regulations have distinguished between drugs for which it makes Medicaid payments using an undiscounted “actual market wholesale price,” and drugs for which it makes Medicaid payments using discounts from the published AWP, which the State characterizes as “significantly inflated” above actual acquisition costs. 24 Ill. Reg. 10436, 10436-37, 10452 (July 1, 2000); ILL. ADMIN. CODE tit. 89, § 140.445.

In this lawsuit, the State nonetheless contends that it was defrauded “until recently” by “false and inflated AWP” because these AWP are “higher than any discount percentage that

¹ Public record materials are included in Defendants’ Appendix for the Court’s judicial notice. *Finish Line Express, Inc. v. City of Chicago*, 72 Ill. 2d 131, 136 (1978).

² As discussed further below, for many drugs, including those that are “multi-source” or “generic” drugs, a drug’s reported AWP may play no role in the reimbursement formula. *See infra* p. 4. The fact that payments for hundreds of drugs are not based on reported AWP is discussed in Certain Defendants’ Supplemental Memorandum of Law Regarding Generic and Multiple Source Drug Products In Further Support of Defendants’ Motion To Dismiss the First Amended Complaint (“Generics Mem.”) being filed simultaneously.

Illinois . . . was using to estimate providers' acquisition costs." (Am. Compl. ¶¶ 48, 50, 52.) It was duped, it asserts, because "[f]or virtually the entire time period relevant hereto," First DataBank, the third party entity that publishes pharmaceutical pricing benchmarks, "represented that its published AWP's reflect actual average wholesale prices." (*Id.* ¶ 47.)

The Amended Complaint should be dismissed in its entirety pursuant to 735 ILCS § 5/2-615, 735 ILCS § 5/2-619(a)(1) and 735 ILCS § 5/2-619(a)(5). *First*, this court should defer consideration of what amounts to the State's challenge to the Medicaid reimbursement system. Such a challenge should be heard, in the first instance, by the Department of Healthcare and Family Services, especially because the relief the State seeks in this case would cause Illinois to be in violation of the federal mandate that prescription drugs be as accessible to Medicaid recipients as they are to the rest of the community.

Second, the Amended Complaint falls far short of satisfying the demanding Illinois fact pleading standards. Although all four Counts of the Amended Complaint are grounded in fraud, the Amended Complaint contains no particularized fact allegations demonstrating an entitlement to relief. The State does not allege what is fraudulent about reporting AWP prices that the State knew for years were "significantly inflated" and therefore discounted. Judicially noticeable public documents and Illinois regulations show that the State had such knowledge. *See, e.g.*, 24 Ill. Reg. 10436 (July 1, 2000). While the State seems to suggest that the Defendants should have somehow reflected the "discount percentage that Illinois . . . was using to estimate providers' acquisition costs" (Am. Compl. ¶ 48.) in the AWP's reported for their drugs, the State provides no facts at all that demonstrate what it contends a "true" AWP should be. In the absence of such particularized pleading of the facts and legal theories entitling it to relief, Defendants and this

Court are left to speculate about what exactly Defendants did that constitutes fraud. The Amended Complaint should therefore be dismissed for this reason alone.

In addition, each Count of the Amended Complaint is defective for failing to adequately plead key elements of each asserted cause of action. The claims under the Consumer Fraud and Deceptive Practices Act (Counts I and II) do not contain required allegations showing “advertising,” “offers to sell,” intent, deception or fraud. In addition, the Attorney General lacks standing to seek actual damages under the Consumer Fraud Act, and has failed to allege facts supporting entitlement to other claimed forms of relief. Count III, brought pursuant to the Public Assistance Fraud Act, is devoid of any allegation sufficient to show the required “benefits or payments” made to any Defendant. Similarly, Count IV, under the Whistleblower Reward and Protection Act, is insufficient to state a claim in that it includes no allegation that any Defendant “presented” any claim, or otherwise violated that Act. Indeed, no information of any sort about what was false about any claim that was actually submitted is provided.

Finally, the Whistleblower Act claims and all statutory penalty claims are barred, in part, by the applicable statute of limitations.

BACKGROUND

Medicaid. Medicaid is a joint federal-state program that provides medical services to low-income individuals. (Am. Compl. ¶¶ 42, 44, 79.) Each State administers its own program, subject to certain federal requirements, and the federal government pays a portion of each State’s costs. See http://www.cms.hhs.gov/MedicaidGenInfo/03_Technicalsummary.asp (last visited November 19, 2007) (Ex. 2.) States have discretion in determining the payment methodology

and payment rate for prescription drugs,³ but – and this is critical – each State is required by federal law to set payment rates at levels “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.” *See* 42 U.S.C. § 1396a(a)(30)(A). Federal law thus requires States, in setting reimbursement rates, to balance the interests of patients, pharmacists, and the government in achieving efficiency, economy, and quality of care. *Id.*

As part of this balancing, a State must pay for pharmaceuticals at the lowest of: (1) the “Federal Upper Limit” (“FUL”) for a particular drug, which is established by the Centers for Medicare and Medicaid Services (“CMS”), the federal agency that administers the Medicare and Medicaid programs;⁴ (2) the estimated acquisition cost, as determined by the State, plus a reasonable dispensing fee; or (3) the provider’s “usual and customary” charges.⁵ *See* 42 C.F.R. § 447.331. A state may set its own “Maximum Allowable Cost” or “MAC” for a drug as its

³ The Complaint treats the Defendants as a monolithic group, failing to recognize the vast differences among the various companies and the products they manufacture. A drug may be self administered or physician administered. Self administered drugs (“SADs”) are prescribed by physicians, dispensed by pharmacies and taken by patients, often in pill or capsule form. Physician administered drugs (“PADs”) are dispensed directly in the physician’s office and include products given through injection or infusion (e.g. cancer treatments). In addition, a drug may be a single source or a multi-source. Single source drugs are sold under a brand name by an innovator company and are generally patent-protected; multi-source drugs are those for which generic equivalents are available. Some defendants manufacture only brand name drugs, others manufacture only generic drugs, while still others manufacture both brand name and generic drugs.

⁴ CMS sets and amends FULs for hundreds of multi-source drugs without reference to AWP. *See* 42 C.F.R. § 447.332.

⁵ The upper limits of FUL and estimated acquisition cost apply to a state’s aggregate payments only; thus, Illinois State Medicaid may choose to pay more than the FUL or estimated acquisition cost (plus a reasonable dispensing fee) for some drugs, and less than the FUL or estimated acquisition cost (plus a reasonable dispensing fee) for other drugs. *See* 42 C. F. R. §§ 447.331-332 (limiting a state’s payments “in the aggregate”) (emphasis added); *see also Nat’l Ass’n of Chain Drug Stores, Inc. v. Bowen*, No. 87-2911, 1989 U.S. Dist. LEXIS 4030, at *5-6 (D. D.C. April 12, 1989) (noting that the upper limit rule “adopts an ‘aggregate’ approach” and permits states “to make payment at levels above the specific standard for certain drugs, provided that the agency makes the payment at levels below the specific standard for other drug products”) (quoting HCFA’s comments to the final rule adopting the upper limit rule, 52 FR 28651).

estimated acquisition cost. Illinois has set MACs for certain drugs. ILL. ADMIN. CODE tit. 89, § 140.445.

States calculate “estimated acquisition cost” differently. Since 1989, Illinois has opted under some circumstances to use benchmark prices called “Average Wholesale Prices” (“AWPs”) published by third party services, minus a percentage, to calculate reimbursement rates. Payment has ranged from AWP minus 7.5% to AWP minus 25%. (Am. Compl. ¶ 48.) For the hundreds of drugs reimbursed at the FUL or MAC, however, AWP is not used in the State’s reimbursement formula. *See id.* ¶ 82; ILL. ADMIN. CODE tit. 89, § 119.60.

In addition to federal funding, the Illinois Medicaid Program also receives federally mandated rebate payments directly from the Defendants that reduce the ultimate cost of the pharmaceuticals. *See* 42 U.S.C. § 1396r-8(a)(1), (b)(2) & (3). The rebate ranges from a minimum of 11% of the particular drug’s Average Manufacturer Price (“AMP”) to considerably more, depending on the drug’s reported “best price.” *See* 42 U.S.C. § 1396r-8(c)(1) & (3). These rebate payments – which are inexplicably ignored in the Amended Complaint – reduce the State’s ultimate costs for Medicaid drugs to levels substantially below its payments to providers. In addition to the federally mandated rebates, Illinois negotiates supplemental rebate agreements directly with Defendants, thereby decreasing the State’s costs even further. *See* 320 ILCS 55/30; *see also* http://www.hfs.illinois.gov/annualreport/reimbursing_pharmacies.html (last visited November 19, 2007) (Ex. 3.)

Key Pricing Terms. The State’s claims focus on the use in the pharmaceutical industry of benchmark “AWPs,” published in third-party reporting compendia. (*E.g.*, Am. Compl. ¶ 46.) For purposes of the Medicaid program, AWP is not defined by statute or regulation, and instead derives its meaning from how it has been used and understood for years by pharmaceutical

manufacturers and payors such as the federal and State governments and private insurers.⁶ The Amended Complaint provides no particulars whatsoever – whether by reference to a statute, regulation, or industry understanding and usage – to support the unstated premise of its claims: that AWP is supposed to represent the providers’ acquisition cost, the price charged by wholesalers to retail pharmacies and doctors. (*See, e.g.*, Am. Compl. ¶¶ 46-48.) This premise is flatly contradicted by an enormous public record of governmental reports concerning AWP. *See infra* pp. 12-17.

The Amended Complaint also sporadically references the term “Wholesale Acquisition Cost” (“WAC”), although there are no allegations about how the State’s Medicaid reimbursement formulas are affected by WAC or how any alleged WAC “inflation” has injured the State. (*E.g.*, Am. Compl. ¶¶ 57, 67.) Federal law defines “wholesale acquisition cost” as “the manufacturer’s benchmark price for the drug or biological to wholesalers or direct purchasers in the United States, *not including prompt pay or other discounts, rebates or reductions in price.*” 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added).

ARGUMENT

I. THE DEPARTMENT OF HEALTHCARE AND FAMILY SERVICES HAS PRIMARY JURISDICTION TO REVIEW THE STATE’S CLAIMS. (735 ILCS § 5/2-619(a)(1))

Although the State’s claims in this action sound in fraud and deception, in reality the State asks this Court to re-set the administratively determined reimbursement rates paid under Medicaid to pharmacists and doctors for thousands of prescription drugs. The State asserts that

⁶ A recent decision of a federal court defined AWP for purposes of the federal Medicare program, which is not at issue in this case. The Court emphasized that the decision was not necessarily applicable to Medicaid. Mem. & Order on Summ. J., *In re Pharm. Indus. Average Wholesale Price Litig.*, MDL No. 1456 (D. Mass. Nov. 2, 2006) (Relating to All Actions) (Ex. 4.)

unless the reimbursement formula set by the Illinois Department of Healthcare and Family Services (formerly known as the Illinois Department of Public Aid) (the “Department”) results in payment for Medicaid drugs equal to providers’ actual acquisition cost, then the State has been defrauded by the companies whose reported benchmark prices the Department utilizes in its formulas. But the Department has never used actual acquisition cost to set reimbursement rates. Instead, as discussed more fully below, it has used AWP discounted by a certain percentage – and it has done so knowing full well that AWP is substantially higher than providers’ actual acquisition cost.

Federal law requires that Medicaid be administered by a single state agency, and in Illinois that agency is the Department. 42 U.S.C.A. § 1396a(a)5; 305 ILCS § 5/5-5.12. The Department has the responsibility to determine payment levels for prescription drugs, subject to federal guidelines.⁷ Accordingly, the Department is charged with determining when the payment formula should be revised, and how, always keeping in mind the need to balance cost minimization against reimbursement levels sufficient to ensure the federally mandated access. The federal government assists each state agency in charge of determining reimbursement formula, by periodically publishing reports regarding reimbursement criteria.⁸

⁷ CMS approves each State’s Plan. *See* 42 U.S.C.A. § 1396.

⁸ *See e.g.*, Dep’t of Health & Human Servs., Office of Inspector Gen., *Medicare Action Transmittal No. 84-12* (Sept. 1984), reprinted in *Medicare & Medicaid Guide* (CCH) § 34,157 at 2 (1984) (Ex. 1.) (explaining that “states can save money under Medicaid by paying for drugs at rates paid by pharmacies, rather than paying the average wholesale price as is often the custom.”); Dep’t of Health & Human Servs., Report of the Office of Inspector Gen., “Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program.” (Oct. 1989) (*Id.* Ex. 5.) (“[I]n August 1989, the Health Care Financing Administration (HCFA) issued a revision to the *State Medicaid Manual* pointing out the preponderance of evidence demonstrating that AWP overstates the prices that pharmacies actually pay for drugs by as much as 10 to 20 percent. The *Manual* issuance provides that, absent valid documentation to the contrary, it will not be acceptable under Medicaid for a state to make reimbursements using AWP without a significant discount.”).

Here, the Attorney General seeks to force Defendants to report as AWP the acquisition cost paid by the ultimate providers of Defendants' drugs. This acquisition cost would then be discounted pursuant to the Department's formulas and a new level of reimbursement will have been set by action of the judicial function, not by the Department.

This is not the proper mechanism by which to accomplish a change in Medicaid payment levels. Such a change should be made in the first instance by the Department. *See, e.g., Donnell v. Woodridge Police Pension Bd.*, 159 Ill. App. 3d 735, 739 (2d Dist. 1987) ("An administrative agency ought to have the opportunity to rule on the issues in the first instance.") (citation omitted). The Department has the unique expertise and authority to make such decisions and has obviously considered the AWP "inflation" the Attorney General challenges in this lawsuit in setting Medicaid pharmaceutical payment at levels that balance the competing issues of cost and provider access. *See e.g.*, 24 Ill. Reg. 10436 (July 1, 2000) (final amendment published at 24 Ill. Reg. 15086 (Oct. 1, 2000)) (documenting that discounts off AWP are justified because AWP are "significantly inflated" above "the 'true' (real) wholesale prices," and cautioning that discounts off of "actual market wholesale prices" "would result in inadequate reimbursement to providers for prescription drugs and the consequent inability of physicians and pharmacies to provide necessary services to the Department's medical assistance clients."). In other words, if this Court were to grant the relief sought by the State, the immediate result would be "inadequate reimbursement to providers" and resultant lack of access to pharmaceuticals for Illinois Medicaid clients. Such a result illustrates precisely why the Department should consider the Attorney General's claims in the first instance.⁹ Pursuant to the doctrine of primary

⁹ It is telling that, nearly three years after the Attorney General brought this action and more than a year after the Attorney General submitted her First Amended Complaint with dozens of specific "average market prices" that, in the State's view, constitute the appropriate Medicaid ingredient reimbursement amount, no change
(Continued...)

jurisdiction, this Court should defer to the jurisdiction of the Department. *Kellerman v. MCI Telecomm. Corp.*, 112 Ill. 2d 428, 445 (1986) (“[Un]der the [primary jurisdiction] doctrine a matter should be referred to an administrative agency when it has a specialized or technical expertise that would help resolve the controversy, or when there is a need for uniform administrative standards.”).

Courts in other States have refused to assume jurisdiction in Medicaid cases. In *Baptist Hospital v. Tennessee Department of Health*, 982 S.W.2d 339 (Tenn. 1998), the Tennessee Supreme Court held that a hospital could not bring an action for Medicaid provider fee damages against the state but must instead seek relief from the Department of Health. The court first observed that federal law requires Medicaid be administered by a single state agency, which in Tennessee was the Department of Health. *Id.* at 341. It characterized the hospital’s claim as one challenging the validity of a state Medicaid regulation, and ruled that the hospital had to go to that single state agency for relief. The court noted that Tennessee’s Department of Health was subject to the state’s administrative procedure act, which is also true of Illinois’ Department of Healthcare and Family Services. *Id.*; *See also* 305 ILCS § 5/12-13. Similarly, in *Pennsylvania Department of Public Welfare v. River Street Associates*, 798 A.2d 260 (Pa. Commw. Ct. 2002), a Pennsylvania appellate court held that the state Medicaid agency had primary jurisdiction over a nursing home’s claim that the agency, with its specific expertise, had violated, misinterpreted, or misapplied its regulations. Dismissing a damages claim, the court held that the agency was the party that should interpret its “complicated method of establishing payment rates and setting

(...Continued)

whatsoever has been made in Illinois Medicaid reimbursement for these drugs. ILL. ADMIN. CODE tit. 89, § 140.445.

payment rates.” *Id.* at 264. For similar reasons, this Court should dismiss this action under the doctrine of primary jurisdiction, or stay proceedings pending a review by the Department.

II. ALL COUNTS SHOULD BE DISMISSED BECAUSE THE AMENDED COMPLAINT FAILS TO SATISFY ILLINOIS FACT PLEADING REQUIREMENTS. (735 ILCS § 5/2-615)

Illinois is “a fact-pleading jurisdiction.” *Hirsch v. Feuer*, 299 Ill. App. 3d 1076, 1081 (1st Dist. 1998). A plaintiff must “allege facts sufficient to bring his claim within the realm of the cause of action asserted.” *Sklodowski v. Countrywide Home Loans, Inc.*, 358 Ill. App. 3d 696, 703 (1st Dist. 2005). Complaints that “rely simply on mere conclusions of law or fact unsupported by specific factual allegations” fail. *Hirsch*, 299 Ill. App. 3d at 1081; *see also Schal Bovis, Inc. v. Cas. Ins. Co.*, 314 Ill. App. 3d 562, 574 (1st Dist. 1999) (“[P]laintiffs must allege facts supporting all of the elements of their claims; notice pleading, conclusions of law, and conclusions of fact are insufficient.”); *Edelman, Combs & Lattuner v. Hinshaw & Culbertson*, 338 Ill. App. 3d 156, 167 (1st Dist. 2003) (“Conclusions of fact will not suffice to state a cause of action[.]”).

The State thus is required to allege specific facts concerning every element of every claim against every defendant. For example, where intent is an element, the plaintiff must allege sufficient facts to establish that intent. *See Martin v. Fed. Life Ins. Co.*, 109 Ill. App. 3d 596, 608 (1st Dist. 1982) (allegation that defendant’s actions were motivated by intent, without facts showing intent is a conclusion). Similarly, where the existence of a duty is an element of a claim, the plaintiff must allege sufficient facts to demonstrate that duty. *See Gouge v. Cent. Ill. Pub. Serv. Co.*, 144 Ill. 2d 535, 542 (1991).

Where, as here, a complaint alleges claims premised on fraud or deception, Illinois law requires even more particularity. *See Chatham Surgicore, Ltd. v. Health Care Serv. Corp.*, 356 Ill. App. 3d 795, 803 (1st Dist. 2005) (“A high standard of specificity is imposed on pleadings

asserting fraud.”); *Hirsch*, 299 Ill. App. 3d at 1085 (same). “The reason for this higher standard is ‘to protect against baseless complaints. This not only weeds out unmeritorious strike suits, but also protects defendants from the harm to their reputations that follows charges of serious wrongdoing.’” *Bd. of Educ. v. A, C & S, Inc.*, 131 Ill. 2d 428, 457 (1989) (quoting *Helfant v. La. & S. Life Ins. Co.* 459 F. Supp. 720, 726 (E.D.N.Y. 1978)). Here, each Count of the Amended Complaint is based in fraud, and thus must meet the heightened pleading standard. *See Kelly v. Sears Roebuck & Co.*, 308 Ill. App. 3d 633, 641-42 (1st Dist. 1999) (“[A] complaint alleging a violation of consumer fraud must be pled with the same particularity and specificity as that required under common law fraud.”).

A. The State Has Failed To Allege What Was Fraudulent About The AWP's Reported For Defendants' Drugs.

The State conclusorily asserts that the Defendants reported “false” or “phony” AWP's. (Am. Compl. ¶¶ 2, 50.) However, the State fails to specify how it contends Defendants' AWP's were “false.” *See People ex rel. Hartigan v. E & E Hauling, Inc.*, 153 Ill. 2d 473, 492 (1992) (“In order to state a claim under the Consumer Fraud Act” the Attorney General “must set forth specific facts which show that defendants misrepresented a material fact[.]”). The State does not point to any statutory or regulatory definition for AWP, nor any representation about a definition made by any Defendant.

The State claims that “First DataBank has represented that its published AWP's reflect actual average wholesale prices.” (Am. Compl. ¶ 47.) But a representation made by First DataBank is not relevant to whether any Defendants made a misrepresentation. *See Zekman v. Direct Am. Marketers, Inc.*, 182 Ill. 2d 359, 369 (1998) (“[K]nowingly receiving the benefits of another's fraud is not actionable under section 2 of the [Consumer Fraud] Act.”). Indeed, the September 1991 Exhibit from First DataBank that the State attaches to the Amended Complaint

makes clear that First DataBank told the State that “[w]holesaler surveys are an important part of what First DataBank does to establish realistic AWP pricing,” and that “First DataBank always publishes the surveyed AWP.” (Am. Compl., Ex. A at R1-019293, R1-019295.) Thus, First DataBank’s alleged representation cannot be converted into a representation by Defendants that the published AWPs reflected actual average wholesale prices. The State has not alleged that Defendants ever represented that their reported AWPs reflected actual average wholesale price or that the understanding of AWP in the pharmaceutical industry was that AWP reflected actual average wholesale price.

Moreover, notwithstanding its contention about what First DataBank represented, the State has not and *cannot* allege that it actually believed that reported AWPs reflected actual average wholesale prices. The Department and federal regulators have long known that AWP is an industry benchmark that is not the same as the pharmacist’s actual acquisition cost. The State admits that, “[c]onsistent with First DataBank’s suggestion that *some* providers were paying less than AWP, Illinois agreed to pay providers an amount consisting of AWP minus a certain percentage (originally 7.5%; currently 12% for brand name drugs and 25% for generic drugs.)” (Am. Compl. ¶ 48.)¹⁰ (emphasis added). If AWP actually equaled the literal average of wholesale prices, reimbursing for certain drugs at 25% *below* AWP would mean reimbursing most (and perhaps all) providers at an amount far *less* than what those providers had paid for

¹⁰ The State provides no facts – particularized or otherwise – supporting its claim that it set the quoted reimbursement rates based on a belief that “some” providers were paying less than AWP. Likewise, no facts are provided showing how the State allegedly determined that the discounts from AWP it selected resulted in payment to providers of actual acquisition cost.

those drugs. This cannot be what the State intended and would not have been a reasonable way to ensure access for Medicaid beneficiaries to prescription drugs.¹¹

In fact, decades of government reports and studies confirm that the State knew that AWP's were only benchmark prices that exceeded, often substantially, acquisition costs. This Court may appropriately take judicial notice of such public record material in the context of a motion to dismiss under 735 ILCS § 5/2-615. *See, e.g., Finish Line Express, Inc.*, 72 Ill. 2d at 136 (“Judicial notice may be taken of such public records” in considering motion to dismiss for failure to state a cause of action); *Nordine v. Ill. Power Co.*, 32 Ill. 2d 421, 428 (1965) (recognizing Illinois courts’ authority to take judicial notice of public records, including the records of state agencies); *Bd. of Managers of Chestnut Hills Condo. Ass’n v. Pasquinelli, Inc.*, 354 Ill. App. 3d 749, 759 (1st Dist. 2004) (“[o]n consideration of a section 2-615 motion” court may properly consider “matters of which the court may take judicial notice”); *Acme Brick & Supply Co. v. Dep’t. of Revenue*, 133 Ill. App. 3d 757, 762 (2d Dist. 1985) (citing *Sturm v. Block*, 72 Ill. App. 3d 306, 312 (3d Dist. 1979) (taking judicial notice of state administrative materials).

The public record here demonstrates that the State cannot state a claim for fraud premised on AWP's not equating to actual acquisition costs. For example, the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) issued a report 22 years ago alerting every state Medicaid agency that, “[w]ithin the pharmaceutical industry, AWP means non-discounted benchmark price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or benchmark price.” *Dep’t. of Health & Human Servs., Office of*

¹¹ The State has also understood that there is no necessary relation between AWP and a pharmacist’s actual acquisition costs. The decision to use AWP minus a specific percentage reflects a political and policy judgment that takes into account numerous factors, including budgetary limitations, administrative convenience, and the need to provide sufficient overall compensation to pharmacies and physicians who dispense drugs to induce them to participate in the Illinois Medicaid Program.

Inspector Gen., Medicare Action Transmittal No. 84-12, reprinted in *Medicare & Medicaid Guide* (CCH) ¶ 34,157 at 2 (Sept. 1984) (Ex. 1.) *See also* HCFA Action Transmittal No. HCFA-AT-77-113 (MMB), Dec. 13, 1977, *Medicaid – Formula For Determining EAC For Drugs*, reprinted in *Medicare & Medicaid Guide* (CCH) ¶ 28,714. (*Id.* Ex. 6) (explaining that AWP prices are marked down and discounted before being used for reimbursement). (*See generally id.* Defs’ App. Exs. 1-9.)

As a result of this universal recognition that AWP did not equal acquisition costs, since at least 1990, state Medicaid programs have been prohibited by the federal government from using undiscounted AWP as a basis for estimating acquisition costs. *See La. v. Dep’t of Health & Human Servs.*, 905 F.2d 877, 879-81 (5th Cir. 1990). An Illinois-specific federal pharmacy study recognized in 1993 that, “[b]ecause pharmacies *routinely receive a discount off of a drug’s AWP*, [federal law] requires states to develop formulas that reimburse pharmacies at prices below AWP.” *See* GAO, “Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland,” at 2 (March 1993) (emphasis added) (Ex. 7).

The consistent conclusions of these governmental studies and reports are clearly reflected in the State’s Medicaid program. The Department has never based Medicaid payments for pharmaceuticals on undiscounted AWP. Its reimbursement formulas have always reflected the knowledge that AWP far exceeded acquisition costs paid by providers. In 1989, for example, when the Department (then known as the Illinois Department of Public Aid) first began using AWP in its Medicaid formula, it paid pharmacies a maximum of AWP minus 7.5% plus a flat dispensing fee. 13 Ill. Reg. 2475, 2494 (Feb. 14, 1989). Within a year, it changed this reimbursement formulary to AWP minus 10% (plus a dispensing fee). *Id.* In 1995, the Department began its practice – which continues today – of distinguishing between brand-name

drugs and multi-source drugs in determining reimbursement rates. Brand-name drugs were then reimbursed at a maximum of AWP minus 10% (plus the dispensing fee) and multi-source drugs were reimbursed at a maximum of AWP minus 12% (plus the dispensing fee). 19 Ill. Reg. 16677 (December 15, 1995). This divergence between the reimbursement rates as measured by AWP discounts for brand-name and multi-source drugs increased in 2001, when the Department changed the Medicaid reimbursement formula so that brand-name drugs were reimbursed at a maximum of AWP minus 11% and multi-source drugs were reimbursed at a maximum of AWP minus 20%. 25 Ill. Reg. 14957, 14973-74 (Nov. 1, 2001). And in 2002, the Department made another change, setting the reimbursement rate for brand-name drugs at a maximum of AWP minus 12% and for multi-source drugs at a maximum of AWP minus 25%. 26 Ill. Reg. 11259, 11276 (July 1, 2002); ILL. ADMIN. CODE tit. 89, § 140.445. (*See also* Am. Compl. ¶¶ 48, 81.) These changing payment rates flatly contradict the fundamental assumption in the Amended Complaint that Medicaid payment rates were based on a belief that AWP's equaled or approximated provider acquisition costs.

In 2000, the Department introduced another regulatory change that further confirms the State's knowledge. As reflected in the HCFA Program Memorandum attached to the Amended Complaint, in May 2000 each State Medicaid program received average wholesale market pricing information "for about 400 national drug codes," which were compiled by the United States Department of Justice ("DOJ") without reliance on published AWP's. (Am. Compl. Ex. B.) Although the States were told that these DOJ wholesale prices themselves exceeded actual acquisition costs, "because purchasers often receive further discounts," *id.*, they nonetheless were significantly lower than published AWP's. In response, the Department amended the Illinois Medicaid regulations, effective July 1, 2000, to take into account these DOJ wholesale

prices by creating a new category of reimbursement where the “price is based upon the *actual market wholesale price*.” 24 Ill. Reg. 10436, 10452 (July 1, 2000) (emphasis added) (final amendment published at 24 Ill. Reg. 15086 (Oct. 1, 2000)). For this category of drugs, where the “average wholesale price” is based on the DOJ “actual market wholesale price,” Illinois Medicaid reimburses pharmacies at that price, with no further discounting, plus a dispensing fee. *Id.* In explaining this regulatory change, the Department confirmed that, when AWP’s are used in reimbursement, a significant discount off AWP (then 10% for brand name products) is justified because AWP’s are “significantly inflated” above “the ‘true’ (real) wholesale prices.” *Id.* at 10436. If the same discount were applied with the lower DOJ “actual market wholesale prices,” however, it “would result in inadequate reimbursement to providers for prescription drugs and the consequent inability of physicians and pharmacies to provide necessary services to Illinois Medicaid’s medical assistance clients.” *Id.* at 10436. To maintain the required access to services, therefore, Illinois Medicaid decided to use the *undiscounted* DOJ “actual market wholesale prices” while maintaining reimbursement for other pharmaceuticals at AWP minus 10% (for brand name drugs) or AWP minus 12% (for multi-source drugs). *Id.* at 10452. This regulatory distinction between wholesale prices “based upon the actual market wholesale price” (reimbursed without further discounts) and published AWP’s (reimbursed at discounts of twelve percent and 25 percent), continues to this day. ILL. ADMIN. CODE tit. 89, § 140.445.¹²

¹² The HCFA Program Memorandum, Ex. B of the Amended Complaint, was suspended by HCFA just *two months* after it was issued. See Dep’t of Health & Human Servs., HCFA Program Mem., PM Rev AB-00-115 (Nov. 2000) <http://www.cms.hhs.gov/transmittals/downloads/AB00115.pdf> (last visited November 2, 2007) (“This is to notify you that you should NOT use the Department of Justice (DOJ) data attached to PM AB-00-86 in your next update of Medicare payment allowances for drugs and biologicals. Instead, until further notice, you should delay use of this new source of average wholesale price (AWP) and use the AWP data from your usual source. While we continue to believe that the AWP’s reported in the usual commercially available sources are inaccurate and inflated above the true wholesale prices charged in the marketplace, congressional action may preclude the use of this alternative source.”) (Ex. 8.)

With this background, the State is unable to, and does not allege that anyone – the State or private consumers – understood AWP to reflect an average of actual acquisition costs for prescription medicines. Without well-pleaded fact allegations of such an understanding, there can be no foundation for any claim grounded in fraud or deception based on a divergence between AWP and provider acquisition cost. Because such an allegation is missing from the Amended Complaint (and, if made, could not pass the “straight face” test in light of the State’s own reimbursement history and decades-long record of reports from the federal government) all four Counts of the Amended Complaint should be dismissed.

B. The State Has Failed To Allege A Duty Owed By Defendants Not To Report AWP That Exceeded Actual Acquisition Cost By More Than The State’s Discount Percentage.

Perhaps wary of its ability to prove a claim based on an expected identity between AWP and provider acquisition cost, the State also complains that Defendants’ published AWP “were higher than any discount percentage that Illinois or any other State was using to estimate providers’ acquisition costs.” (Am. Compl. ¶ 48.) This tacit admission that the State did not rely on AWP equaling providers’ acquisition cost illustrates that the State’s conclusory claims that the Defendants reported “false” AWP is so lacking in specificity as to be meaningless.

If the State maintains that AWP should be no more than a certain percentage above the actual average wholesale price, then the State must allege what that percentage should be. Moreover, the State must allege where any such requirement came from. There are no allegations demonstrating a duty by Defendants to report an AWP exceeding actual acquisition cost by no more than a particular State’s payment discount. As explained by a Wisconsin Circuit Court evaluating a similar AWP complaint filed in Wisconsin, “[u]nder this complaint, it is not known what Plaintiff considers the threshold for fraud. Would a few cents difference from the AWP and the actual sales price meet that definition? A few dollars?” *Wis. v. Amgen Inc.*, No.

04-CV-1709, slip op. at 13 (Wis. Cir. Ct. April 3, 2006) (Ex. 9.) Here, is it 7%? 12%? 25%? Or does the threshold for fraud vary with the percentage off of AWP that the State was paying to providers at a particular time? The spreadsheet the State attaches to the Amended Complaint does not answer these questions. Many of the challenged “spreads” on Exhibit C are less than the 25% discount from AWP the State paid for some drugs at some times, and scores of others are within a few percentage points of 25%. The State’s failure to define its conclusory claims of “inflated” or “fraudulent” AWP, does not even give Defendants fair notice of the claims against them, let alone the facts they are entitled to in Illinois.

C. The State Has Failed To Specify Each Defendant’s Role In The Alleged Fraud.

The Amended Complaint repeatedly lumps all forty-plus Defendants together in rote allegations of fraud, without specifying actual conduct by individual Defendants. Such group pleading does not provide the particularity required by 735 ILCS § 5/2-603(a), or otherwise meet the pleading standards for fraud-based claims. *See Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 501 (1996); *Petrich v. MCY Music World, Inc.*, 371 Ill. App. 3d 332, 343 (1st Dist. 2007) (finding that the complaint failed to state a claim for consumer fraud because “[p]laintiff’s allegations fail to state with the required specificity what misrepresentations were made, by whom and to whom, when or how they were made.”). In cases involving multiple defendants and representations, the complaint must inform *each defendant* of its alleged wrongdoing. *See A, C, & S, Inc.*, 131 Ill. 2d at 457-58. (dismissing fraud claims against multiple defendants because complaint failed to specify actions by individual defendants); *Exch. Nat’l Bank v. Farm Bureau Life Ins. Co.*, 108 Ill. App. 3d 212, 215 (3d Dist. 1982) (fraud claim properly dismissed for failure to plead with specificity where “[a]lthough eight officers are named as defendants, the complaint does not delineate which person is responsible for what conduct.”); *Cf. Vicom, Inc. v.*

Harbridge Merch. Servs., Inc., 20 F.3d 771, 777-778 (7th Cir. 1994) (complaints that “lump together” multiple defendants do not satisfy Fed. R. Civ. P. 9(b)).

Rather than identify specific wrongful conduct, the State charges all Defendants in conclusory group-based allegations, such as:

- “Defendants often market their products by pointing out (explicitly and implicitly) that their drug’s spread is larger than the spread of a competing drug.” (Am. Compl. ¶ 51.)
- “Defendants have defeated the intent of the Medicaid program to pay providers no more than their acquisition cost by reporting false and inflated AWP’s to First DataBank and/or by reporting prices that they knew, because of the manner of First DataBanks’ operations, would misrepresent defendants’ true wholesale prices.” (*Id.* ¶ 50.)
- “As they have done with their AWP’s, defendants have illegally and deceptively misrepresented and inflated the wholesale acquisition cost (“WAC”) of their drugs.” (*Id.* ¶ 57.)

But no allegations regarding which Defendants engaged in the challenged marketing practices are provided.¹³ The Amended Complaint does not distinguish between Defendants alleged to have actually reported “false and inflated AWP’s” versus those alleged to have reported prices they allegedly knew First DataBank would then “misrepresent.” The State does not even plead which Defendants it claims misrepresented WACs in addition to or instead of AWP’s.

In dismissing a similar AWP complaint brought by the Attorney General in Pennsylvania (another “fact pleading” state), the *en banc* Pennsylvania Commonwealth Court found precisely the same type of pleading failure that exists here; it held that the Commonwealth’s complaint did not “differentiate the specific conduct of each Defendant,” and failed “to discriminate with regard to the conduct of each Defendant, as to the manner of fraud, and their drugs.” *Commw. ex*

¹³ This Court addressed a similar issue with respect to lack of specificity and “lumping” defendants in *People ex rel. Donaldson & the State of Ill. v. MIDI, LLC et al*, No. 06 CH 2513 (Report of Proceedings at 90, Sept. 11, 2007.) on a motion to dismiss.

rel. Pappert v. TAP Pharm. Prods., Inc., 868 A.2d 624, 636 (Pa. Commw. Ct. 2005). Likewise, in an AWP case in Wisconsin (a “notice pleading” state), in which the State is represented by the same private law firm that signed the Amended Complaint in this case, the Court required the State to amend because of similar pleading failures. *Amgen, Inc.*, No. 04-CV-1709, slip op. at 13 (Ex. 9.). The Wisconsin court gave the following directive:

In order to maintain these causes of action premised on fraud, Plaintiff must re-plead them, giving as many specifics as it can. Each Defendant is entitled to know, with as much detail as Plaintiff can provide, **which** of its drugs are involved and **what** (name, date) publication of AWP is false, and the **actual** price that should have been published.

Id. (emphasis in original).

The Wisconsin court also chided the State for alleging that “some defendants have hidden their real drug prices by providing free drugs and phony grants to providers as a means of discounting the overall price of their drugs.” The Court held that this paragraph “takes the vagueness of this pleading to dangerous levels[.]” *Id.* at 13 n.11. The language so condemned by the Wisconsin court, however, appears once more almost verbatim in the Amended Complaint here, where fact-pleading and not merely notice-pleading is required. (Am. Compl. ¶ 64.)

The State’s only apparent effort to provide some specificity is contained in Exhibit C, which purports to list the allegedly false AWP’s, the market price, and “the spread between the market price and the AWP” for certain drugs for certain Defendants. (*Id.* ¶ 56.) This exhibit is not sufficient to cure the numerous pleading defects set out above. *First*, there are missing values for many of the drug NDC numbers listed. Not only is the “average market price” missing for those drugs, but the reported AWP is missing. (See for example: Abbott, NDC No. 0007471265; Amgen, NDC No. 55513001104; AstraZeneca, NDC No. 00310070539; Roxane, NDC No. 0054354258). It is hard to understand how the State can allege that the AWP’s

for those drugs were “fraudulent” or “inflated” when it does not know what the AWP for those drugs were.

Second, Exhibit C lists only alleged misrepresentations for the years 2001-2003, even though the State seeks damages for fraudulent conduct from 1993 to the present. Without particularized facts regarding the alleged false AWP prior to 2001 and after 2003, the State has failed to plead fraud for those years.

Third, even though the State alleges that the Defendants also reported fraudulent WACs, Exhibit C contains *no mention* of what the allegedly fraudulent WACs were or what the non-fraudulent WAC should have been. If the State’s case involves WAC in addition to AWP, it is required to plead its WAC case with specificity as well.

Fourth, no facts regarding the State’s apparent *parens patriae* claims based on Medicare co-payments are included in Exhibit C or elsewhere. Indeed, it is impossible even to tell which Defendants the State claims are liable for Medicare-based claims. And no facts supporting the implication that Medicare co-payments were “inflated” as a result of “fraudulent” AWP are alleged.

Finally, there is no indication of whether the State actually reimbursed any of the drugs listed on Exhibit C based on AWP. According to the Complaint, the State must reimburse providers at their “usual and customary charges to the general public,” when that amount is lower than the sum of the State’s EAC plus dispensing fees. (Am. Compl. ¶ 44.) There also are hundreds of multi-source drugs that are reimbursed on FULs or MACs, not AWP.¹⁴

¹⁴ See Generic Mem. at 6-7.

III. COUNTS I AND II SHOULD BE DISMISSED BECAUSE THE STATE FAILS TO STATE A CLAIM UNDER THE CONSUMER FRAUD AND DECEPTIVE PRACTICES ACT. (735 ILCS § 5/2-615)

In Counts I and II of the Amended Complaint, the State fails to state claims under two separate sections of the Illinois Consumer Fraud and Deceptive Practices Act (“the CFA”): (1) Section 2 – Unlawful Practices, 815 ILCS § 505/2; and (2) Section 2CC(b) – Wholesale Advertising, 815 ILCS § 505/2CC.

A. The State Has Not Adequately Alleged An Unfair Or Deceptive Act Or Practice, Intent, Or A Basis For Penalties.

Section 2 of the CFA prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . .” 815 ILCS § 505/2. To state a claim under this section a plaintiff must allege “(1) a deceptive act or practice by the defendant; (2) the defendant’s intent that the plaintiff rely on the deception; and (3) the occurrence of the deception during a course of conduct involving trade or commerce.” *Robinson v. Toyota Motor Credit Corp.*, 201 Ill. 2d 403, 417 (2002). The allegations must “state with particularity and specificity the deceptive manner of defendant’s acts or practices, and the failure to make sure averments requires the dismissal of the complaint.” *Id.* at 419.

As explained *supra*, in section II.A., the conduct alleged in the Amended Complaint does not violate Section 2 of the CFA because it does not constitute fraud or deception. Nor has the State adequately alleged concealment sufficient to constitute deception. No action for concealment will lie unless the plaintiff alleges that the defendants knowingly concealed a material fact in the course of trade or commerce. *White v. DaimlerChrysler Corp.*, 368 Ill. App.

3d 278, 286 (1st Dist. 2006). Plaintiffs are required to allege with specificity that – and how – they would have acted differently had they known the concealed fact. *Id.* (affirming dismissal of CFA concealment claim where the plaintiff failed to state that he would have acted differently); *Perez v. Citicorp. Mortgage, Inc.*, 301 Ill. App. 3d 413, 420 (1st Dist. 1998) (“[T]he concealed fact must be such that, had the other party been aware of it, he would have acted differently.”) (citations omitted); *See also Connick*, 174 Ill. 2d at 505. The State has made no allegations that it would have acted differently, much less *how* it would have acted differently, had it been “aware” that AWP’s did not equal the “true price of [Defendants’] drugs.” (Am. Compl. ¶ 67.) In fact, as indicated *supra*, in Section II.A., the State could not even plausibly make such allegations, because it was aware that AWP’s did not equal providers’ actual acquisition cost. Moreover, when the State clearly had the opportunity to act differently – since it initiated this litigation, at the very latest – it chose not to do so. To this day, Illinois Medicaid reimbursement for these drugs remains unchanged. *See supra*, Section I; ILL. ADMIN. CODE tit. 89, § 140.445.

But beyond this failure to adequately allege any acts of fraud or deception, the State has not alleged the factual basis for its conclusory allegation that Defendants actually intended for the State “and others” to “rely on their deceptive conduct.” (Am. Compl. ¶ 100.) Indeed, the State omits the requirement that a defendant has acted “with intent that others rely” completely out of its quotation of the statute. *See id.* ¶ 99. Without factual allegations sufficient to support the conclusion of “intent,” there can be no viable claim under Section 2 of the CFA. *People ex rel. Hartigan v. E & E Hauling, Inc.*, 153 Ill. 2d 473, 500 (1992) (affirming dismissal of claim that defendant violated CFA where plaintiff failed to allege intent to induce reliance).

Finally, the State’s claim in Count I for penalties under Section 505/7(b) and (c) of the CFA for “each violation” must be stricken because of the total absence of facts showing the

“intent to defraud” required under Section 505/7(b), or any of the factors that justify penalties for violations committed against persons 65 years of age or older under Section 505/7(c).¹⁵ In the absence of such allegations, there is no legal basis for the State’s claim to such penalties.

B. The State Has Not Pled The Advertisement And Offer To Sell Required To State A Claim Under Section 2CC(b).

Section 2CC(b) of the CFA prohibits a person from representing “directly or by implication *in any advertising* that a person *offers to sell or sells* a particular article of merchandise at a wholesale price unless that person can substantiate significant savings on his price as compared to identical merchandise *offered for sale by retailers* in the trade area.” 815 ILCS § 505/2CC(b) (emphasis added). Section 2CC(b) does not apply to the conduct alleged. The State has not alleged that Defendants have advertised AWP or any fraudulent price. In fact, the Amended Complaint makes no mention of advertising at all. The State simply jumps from its description of the prohibitions of Section 2-CC(b) in paragraph 103 of the Amended Complaint to the conclusory allegation in paragraph 104 that “causing to be published” false wholesale prices violates Section 2-CC(b) of the CFA.¹⁶

¹⁵ Section 505/7(c) of the CFA provides that a Court must consider the following factors in determining whether a penalty is warranted:

- (1) Whether the defendant’s conduct was in willful disregard of the rights of the person 65 years of age or older.
- (2) Whether the defendant knew or should have known that the defendant’s conduct was directed to a person 65 years of age or older.
- (3) Whether the person 65 years of age or older was substantially more vulnerable to the defendant’s conduct because of age, poor health, infirmity, impaired understanding, restricted mobility, or disability, than other persons.
- (4) Any other factors the court deems appropriate.

¹⁶ Paragraph 104 of the Amended Complaint is hard to decipher. Its haphazard juxtaposition of wholesale and retail pricing references is at best misleading, especially since the State has not pled any retail prices. This paragraph is a wholly insufficient basis for the claim in Count II.

Plaintiff's allegations are defective as a matter of law. Contrary to the State's erroneous assertion, Illinois has not "specifically declared that it is a deceptive practice to represent directly or by implication" that a person sells at a wholesale price unless that price is less than that offered by retailers. (Am. Compl. ¶ 93.) Illinois has specifically outlawed such practice "in any advertising." 815 ILCS § 505/2CC(a) and (b). The advertising referred to in Section 2CC(b) of the CFA – a consumer protection statute – can only be advertising of prices directed at purchasing consumers – not at prices reported in industry compendia a consumer would never see. Moreover, to be actionable, the "advertising" must include an offer to sell, or a representation that the advertiser sells a product to consumers at a price less than that at which other retailers sell the identical product. *Id.* There are no allegations in the State's Amended Complaint that any Defendant offered or sold any products at AWP falsely representing AWP to be less than the retail price. For these reasons, Section 2CC(b) is simply inapplicable to the conduct alleged in the Amended Complaint.

C. The Prayers For Actual Damages In Counts I and II Should Be Dismissed Because The Attorney General Has No Standing To Bring Them.

In both Counts I and II, the State seeks declaratory relief, injunctive relief, restitution, civil penalties, attorneys' fees and *actual damages*. However, as the State implicitly concedes in the Amended Complaint, the authority of the Attorney General to bring an action under the Consumer Fraud Act stems only from Section 7 of the Act. (Am. Compl. ¶ 3.); 815 ILCS § 505/7. Section 7 does not authorize recovery of actual damages. The only section in the Consumer Fraud Act that allows recovery of actual damages is Section 10a, and only a "person" may bring a private action under Section 10a. *See* 815 ILCS § 505/10a(A) ("Any *person* who suffers actual damage as a result of a violation of this Act committed by any other person may bring an action against such person.") (emphasis added). "Person" is defined in the CFA as:

“any natural person or his legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof[.]” *Id.* § 505/1(c). The Attorney General does not fit that definition. *See Du Page Aviation Corp. v. Du Page Airport Auth.*, 229 Ill. App. 3d 793, 805 (2d Dist. 1992) (“The [DuPage Airport Authority] is a municipal corporation, does not fall within the definition of ‘person’ in the [Consumer Fraud] Act, and is therefore not subject to suit under the Act.”); *A, C, & S, Inc.*, 131 Ill. 2d at 467-69 (school districts are not included in the definition of “person” and therefore may not bring an action under Section 10a of the Consumer Fraud Act). The Illinois Supreme Court explained, in *A, C, and S* that

[I]n enacting the Consumer Fraud Act the legislature expressly limited its application to ‘any *natural* person’ and not to the broader ‘person’ . . . The Consumer Fraud Act clearly makes an unusual distinction that the Act only applies to domestic and foreign corporations. A body politic or municipal entity is neither type of corporation, and we believe that such an interpretation would again ignore language within the Act . . . Thus, the legislature is aware of how to include a body politic within the definition of ‘person’ or ‘corporation,’ and we believe that its failure to do so in the Consumer Fraud Act shows an intent not to include them within the definition of persons who may sue based on the Act.”

Id.

Accordingly, the State cannot bring an action under Section 10a of the CFA. And that Section provides the only basis for a claim for actual damages.

IV. COUNT III UNDER THE ILLINOIS PUBLIC ASSISTANCE FRAUD ACT SHOULD BE DISMISSED BECAUSE DEFENDANTS SUBMITTED NO “CLAIMS” FOR PAYMENT. (735 ILCS § 5/2-615)

Plaintiff purports to bring Count III of this action under Section 7(b) of the Illinois Public Assistance Fraud Act (“IPAFa”) 305 ILCS § 5/8A-7(b). Section 7(b) of the IPAFa provides a civil remedy when a defendant “willfully” obtains or attempts to obtain through fraud or misrepresentation “benefits or payments” from the State “to which he or it is not entitled.” *Id.*

As a threshold matter, and as set out in Section II.A. above, the State has not sufficiently alleged misrepresentation or fraud. In addition, none of the Defendants is alleged to have received *any* Medicaid benefits or payments under the State program. The Amended Complaint asserts that the State made the alleged “overpayments” to Illinois pharmacies, physicians and hospitals/clinics, not to Defendants. (Am. Compl. ¶¶ 50, 66.) In fact, the State alleges only that “defendants have *caused damages* to the Illinois Medicaid program in that plaintiff has paid far more for defendants’ drugs than they would have paid had defendants truthfully reported the AWP of their drugs” (*id.* ¶ 109) (emphasis added), not that Defendants received any benefits or payments. This allegation is not a sufficient factual basis on which to state a claim under the IPFA as it does not satisfy the plain language of that statute. Count III should therefore be dismissed.

V. COUNT IV UNDER THE WHISTLEBLOWER REWARD AND PROTECTION ACT FAILS BECAUSE DEFENDANTS SUBMITTED NO “CLAIMS” FOR PAYMENT. (735 ILCS § 5/2-615)

The State brings Count IV under three sections of the Illinois Whistleblower Reward and Protection Act (“Whistleblower Act”),¹⁷ 740 ILCS § 175/3: Section 1 (liability for any person who submits or causes to be submitted to the State false or fraudulent claims for payment), Section 2 (liability for a person who makes or uses false statements to get a false or fraudulent claim paid), and Section 7 (liability for a person who makes or causes to be made a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State). *Id.* (a)(1), (2), (7). Plaintiff has failed to state a claim under any of these sections. The Amended Complaint contains *no* allegations concerning any obligation on the part of any

¹⁷ The Whistleblower Act closely tracks the federal False Claims Act. *Scachitti v. UBS Fin. Serv.*, 215 Ill. 2d 484, 507 (2005).

Defendant to pay or transmit money or property to the State, let alone the use of a false record or statement to avoid such obligation. This basic failure to allege the elements required under Section 7 requires dismissal of that claim.

In addition, the State has not alleged facts necessary to state a claim under either Sections 1 or 2. Each of those sections requires allegations showing false claims submitted to and/or paid by the State. Most basically, the State does not attach a single allegedly false claim to its complaint to illustrate to the Defendants and the Court what precisely on the claim form itself is “false.” Nor has the State specified what was fraudulent about the Defendants’ reported AWP’s, as explained *supra*, in Section II.A.

Moreover, where the party alleged to be deceived authorized the pricing or reimbursement utilized by the defendant, there can be no false claim. *See, e.g., United States v. Bruno's Inc.*, 54 F. Supp. 2d 1252, 1260 (M.D. Ala. 1999). In *Bruno's*, the plaintiff alleged that defendant pharmacies fraudulently charged Alabama Medicaid a higher dispensing fee for prescriptions than it charged Blue Cross-Blue Shield of Alabama. The Court found there was no fraud because plaintiff “completely ignores the fact that it is the Alabama Medicaid agency itself, and not Defendants, that sets the amount of the dispensing fee. Defendants merely charge the fee Medicaid tells them to charge.” *Id.* at 1260 (citation omitted). *Accord, United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1075 (9th Cir. 1998) (Veterans Administration policy authorized funded resident system and therefore clinic's reimbursement for compensation of residents was not false claim); *United States ex rel. Glass v. Medtronic, Inc.*, 957 F.2d 605 (9th Cir. 1992) (medical device manufacturer's Medicare claim was authorized by Medicare manual and therefore not a false claim). Here, it is Illinois Medicaid that set AWP as a reimbursement

standard. Illinois cannot contend any fraud has been committed when the providers have been paid consistent with Illinois Medicaid's regulations.

Section 1 also requires that the Defendants presented a claim, or that they “caused” a claim to be presented. The State has made *no* such allegations. The State has only alleged that the Defendants reported inflated AWP’s to a reporting service that then published them. Any contention by the State that the reports of AWP’s to third-party publishers are “false claims” under the Act fails because no Defendant requests or attempts to request payments from Illinois Medicaid. *See People ex. rel. Levenstein v. Salafsky*, 338 Ill. App. 3d 936, 943 (2d Dist. 2003) (“A person violates [the Whistleblower Act] . . . if (1) he makes a ‘claim’ . . . and (2) he uses a false record or statement to get that claim *paid* . . . by the State.”) (emphasis in original); *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (holding no federal False Claims Act liability unless false statement is used to get a payment from the government). If, instead, the alleged “false claims” are Medicaid claim forms submitted to the State by pharmacies and doctors, then the claim fails because the Amended Complaint does not sufficiently allege how each Defendant “caused” pharmacies and doctors to submit such false Medicaid claims within the meaning of the Act. *See United States v. Bornstein*, 423 U.S. 303, 312-13 (1976) (“The Act, in short, penalizes a person for his own acts, not for the acts of someone else. . . . [T]he focus in each case [must] be upon the specific conduct of the person from whom the Government seeks to collect the statutory forfeitures.”). At best, the State avers (inadequately and collectively) that Defendants’ false AWP’s allowed others to submit false claims for payments from Illinois Medicaid. Yet, “[e]ven a claim that the defendant ‘caused some of the circumstances that led to the submission of the false claims’ will not satisfy the requirement of pleading that the defendant *caused* a false claim to be made.” *United States ex*

rel. Grynberg v. Ernst & Young LLP, 323 F. Supp. 2d 1152, 1155 (D. Wy. 2004) (citing cases) (quoting *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, No. 94-7316, 2000 U.S. Dist. LEXIS 12081, at *54 (E.D. Pa. Aug. 24, 2000)). Accordingly, any claims under Section 1 and 2 of the Whistleblower Act should be dismissed.

VI. THE STATE'S CLAIMS IN COUNT IV ARE BARRED IN PART BY THE APPLICABLE STATUTE OF LIMITATIONS. (735 ILCS § 5/2-619(a)(5))

Statute of limitations may be asserted against the State when the right the State seeks to assert belongs only to the government or to "some small and distinct subsection of the public at large." *City of Shelbyville v. Shelbyville Restorium, Inc.*, 96 Ill. 2d 457, 461-462 (1983). Thus, all of the Attorney General's claims brought in her *parens patriae* capacity on behalf of Illinois citizens who are Medicare Part B participants are subject to the applicable statute of limitations. Accordingly, the State's claims on behalf of Illinois citizens for statutory penalties (Counts I - IV) are barred to the extent they arose before February 7, 2003. 735 ILCS § 5/13-202 ("Actions for ... a statutory penalty ... shall be commenced within 2 years next after the cause of action accrue[.]").

CONCLUSION

For the foregoing reasons, the State's First Amended Complaint should be dismissed in its entirety.

Dated: November 19, 2007

Respectfully submitted,



Helen E. Witt, P.C. (Bar No. 6183630)
Elizabeth S. Hess (Bar No. 6283085)
Ceylan Ayasli Eatherton (Bar No. 6285674)
Miriam L. Lieberman (Bar No. 6293227)
KIRKLAND & ELLIS LLP
Firm No. 90443
200 East Randolph Drive
Chicago, Illinois 60601
Telephone: (312) 861-2000
Facsimile: (312) 861-2200

*Attorneys for Defendants
Ben Venue Laboratories, Inc.
Boehringer Ingelheim Pharmaceuticals, Inc.
and Boehringer Ingelheim Roxane, Inc. and
on behalf of all joining Defendants*

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS,)	
)	
Plaintiff,)	
)	No. 05 CH 2474
v.)	
)	The Honorable Peter Flynn
ABBOTT LABORATORIES, INC., <i>et al.</i> ,)	
)	
Defendants.)	

CERTIFICATE OF SERVICE

I, Ceylan Ayasli Eatherton, an attorney, hereby certify that on this 19th day of November, 2007, true and correct copies of (1) Defendants' Joint Motion to Dismiss Plaintiff's First Amended Complaint, (2) Defendants' Joint Memorandum of Law in Support of Their Motion to Dismiss Plaintiff's First Amended Complaint, and (3) Defendants' Exhibits, were served on all counsel of record via LexisNexis File and Serve pursuant to this Court's Order dated June 2, 2006.

Dated this 19th day of November, 2007.



Ceylan Ayasli Eatherton